

NOVEL CRYSTALLINE FORMS OF CANDESARTAN CILEXETIL

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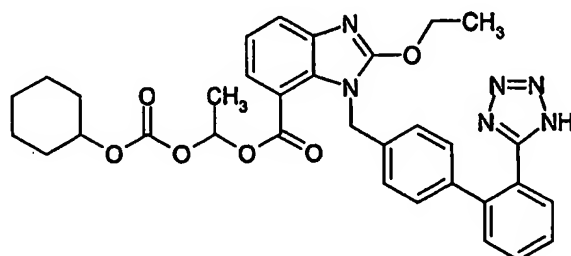
FIELD OF THE INVENTION

- 5 The present invention relates to two novel crystalline forms and a novel 1,4-dioxane solvate of candesartan cilexetil, to processes for their preparation and to pharmaceutical compositions containing them.

BACKGROUND OF THE INVENTION

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Candesartan cilexetil of formula (1):



- 15 or 2-Ethoxy-1-[[2'-(1H-tetrazol-5-yl)][1,1'-biphenyl]-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, 1-[[[(Cyclohexyloxy)carbonyl]oxy]ethyl] ester. Candesartan cilexetil is an antihypertensive agent and its therapeutic uses were disclosed in US 5,196,444. US 5,196,444 also disclosed a crystalline form of candesartan cilexetil (C-type crystalline form). Two crystalline forms of
20 candesartan cilexetil, form I and form II, are described in Chem. Pharm. Bull. 47(2), 182-186 (1999).

We have discovered a novel 1,4-dioxane solvate of candesartan cilexetil and two novel crystalline forms of candesartan cilexetil. The novel forms have been found to be stable and reproducible.

- 25 The object of the present invention is to provide a stable novel 1,4-dioxane solvate of candesartan cilexetil and two stable crystalline forms of candesartan cilexetil, processes for preparing these forms and pharmaceutical compositions containing them.